DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 11, 2014

LiNA Medical ApS
Anne Klitgard
QA/RA Manager
Formervangen 5
Glostrup, Demark, DK-2600

Re: K1413145
Trade/Device Name: SafeAir Smoke Pencil
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 31, 2014
Received: November 3, 2014

Dear Ms. Klitgard,

This letter corrects our substantially equivalent letter of 12/4/2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143145

Device Name
SafeAir Smoke Pencil

Indications for Use *(Describe)*

The SafeAir Smoke Pencil is designed for general electrosurgical applications including cutting and coagulation and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Applicant: LiNA Medical ApS
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Date Summary Prepared: 29 October 2014

Trade Name: SafeAir Smoke Pencil

Common Name: Electrosurgical cutting and coagulation device and accessories

Classification Data: 21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories, Product Code GEI, Class II 510(k)

Reason for 510(k) Submission: Special 510(k) – device modifications and line extension with no change to fundamental scientific technology or intended use.

Device Modification: LiNA Medical ApS submits this Special 510(k) for the SafeAir Smoke Pencil. The modifications are as follows.

- Modification of electrode connector material for coated blade electrode
- Addition of clip and holster accessories to the package
- The 70 mm blade electrodes (coated and uncoated) and suction sleeve will be provided pre-mounted onto the pencil

The modifications change neither the intended use, the indications for use, nor the fundamental scientific technology of the system.

Line Extension: The line of electrodes offered for use with the SafeAir Smoke Pencil will be expanded to include the following configuration:

- Blade electrode, coated, 70 mm length

The line extension does not change the intended use, indications for use, or the fundamental scientific technology of the system.

Predicate SE Device: SafeAir Smoke Pencil, K142538

Indications for Use:

The SafeAir Smoke Pencil is designed for general electrosurgical applications including cutting and coagulation and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

Device Description:

The SafeAir Smoke Pencil is a sterile, single-use, integrated electrosurgical pencil and smoke evacuation handpiece. The device is designed for general electrosurgical applications and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The integration of the electrosurgical pencil and smoke evacuation enables the operator to activate an electrosurgical current as well as capture smoke plume simultaneously.

The SafeAir Smoke Pencil is available in two activation switch configurations, a rocker style and push-button style, which activate monopolar cut or coagulate functions. The pencil is connected to smoke evacuation tubing which features a dual connector (8 and 22 mm) to allow the user to connect to a variety of smoke evacuation systems including filtration or central vacuum systems, thus minimizing exposure of personnel to surgical smoke plume. Electrodes are available in either 70 mm blade or 70 mm coated blade configurations.

Device Models:

Description	Part Numbers
SafeAir Smoke Pencil with 70 mm blade electrode	SHK-VS-TS
SafeAir Smoke Pencil with 70 mm blade electrode, rocker button style	SHK-VS-RS-TS
SafeAir Smoke Pencil with 70 mm coated blade electrode	SHK-VS-C-TS
SafeAir Smoke Pencil with 70 mm coated blade electrode, rocker button style	SHK-VS-RS-C-TS

Performance Data (Non-Clinical Tests):

The results of performance testing demonstrate that the functionality, integrity, and safety and effectiveness of the SafeAir Smoke Pencil and electrodes are sufficient for their intended use and support a determination of substantial equivalence.

Summary of Performance Testing:

Biocompatibility testing was performed on the subject device in accordance with ANSI/AAMI/ISO 10993-1:2009: Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing. Results of testing validate the subject device is biocompatible as intended for use.

The SafeAir Smoke Pencil is available only in sterile packaged form. The sterile product will be terminally sterilized using ethylene oxide (EO). The sterilization method was validated and performed in accordance with ANSI/AAMI/ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide. A sterility assurance level of 10^{-6} has been validated for this product.

Performance testing was conducted on the subject devices as determined by the risk analysis of the product. The following areas were evaluated:

- Electrical safety testing
- Integrity and functionality testing after aging
- Thermal spread testing
- Biocompatibility testing
- Sterilization and packaging testing

Predicate Comparison:

	Description	SafeAir Smoke Pencil (Subject)	SafeAir Smoke Pencil, K142538 (Predicate)	Explanation of Difference
Regulatory Information	**510(k) Number**	Not yet assigned	K142538	N/A
	Product Code	GEI	GEI	Same
	Regulation Number	21 CFR 878.4400	21 CFR 878.4400	Same
	Regulation Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	Same
	Product Classification	Class II	Class II	Same
	Indications for use	The SafeAir Smoke Pencil is designed for general electrosurgical applications including cutting and coagulation and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.	The SafeAir Smoke Pencil is designed for general electrosurgical applications including cutting and coagulation and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.	Same
Overall Design Concept	**Overall Design**	Device designed to integrate smoke evacuation into electrosurgery by combining both features into a single handpiece	Device designed to integrate smoke evacuation into electrosurgery by combining both features into a single handpiece	Same
	Power supply	Monopolar generator supplied by user	Monopolar generator supplied by user	Same
	Monopolar Generator Setting	Maximum 6 kV peak	Maximum 6 kV peak	Same
	Electrical Connector	US-3-Pin	US-3-Pin	Same
	Electrical Safety Testing	ISO 60601-1 ISO 60601-2-2	ISO 60601-1 ISO 60601-2-2	Same

	Description	SafeAir Smoke Pencil (Subject)	SafeAir Smoke Pencil, K120454 (Predicate)	Explanation of Difference
	Sterility	Sterile, single use only Sterilized by Ethylene Oxide gas Sterility Assurance level = 10^{-6}	Sterile, single use only Sterilized by Ethylene Oxide gas Sterility Assurance level = 10^{-6}	Same
	Packaging	Single pencil unit with preassembled blade and suction sleeve, holster, and clip in an individual Tyvek sealed pouch, sold 10 per box.	Single pencil unit with blade, in an individual Tyvek sealed pouch, sold 10 per box.	Similar – Blade and suction sleeve are preassembled, holster and clip included.
Electrode Technology and Materials	**Electrode rod material**	Stainless steel	Stainless steel	Same
	Electrode rod diameter	2.4 mm (3/32 inches)	2.4 mm (3/32 inches)	Same
	Electrode connector material	Polypropylene	Polypropylene	Similar – polypropylene connector for coated blade is supplied from a different source than cleared connector material.
	Electrode coupler shape (all electrodes)	Pentagonal	Pentagonal	Same
	Electrode, blade material	Stainless steel	Stainless steel	Same
	Electrode, blade coating (if present)	Polytetrafluoroethylene (PTFE)	N/A	Coating is being introduced in this submission.
	Electrode Length	70 mm	70 mm	Same

	Description	SafeAir Smoke Pencil (Subject)	SafeAir Smoke Pencil, K120454 (Predicate)	Explanation of Difference
Smoke Evacuation Materials and Technology	**Adjustable Suction Sleeve Material**	Styrene butadiene copolymer Acrylonitrile butadiene styrene with barium sulfate	Styrene butadiene copolymer Acrylonitrile butadiene styrene with barium sulfate	Same
	Evacuation Tubing Dimension	10 mm diameter X 3 m length	10 mm diameter X 3 m length	Same
	Smoke Evacuation System Connector	8 mm, 22 mm	8 mm, 22 mm	Same
Pencil Technology and Materials	**Handpiece Housing Material**	Acrylonitrile Butadiene Styrene with Thermoplastic Elastomer	Acrylonitrile Butadiene Styrene with Thermoplastic Elastomer	Same
	Handpiece Dimension	15 mm diameter X 190 mm length	15 mm diameter X 190 mm length	Same
	Operation Function Switches	CUT button labeled yellow and proximal to electrode COAG button labeled blue and distal to electrode	CUT button labeled yellow and proximal to electrode COAG button labeled blue and distal to electrode	Same

Conclusion/Substantial Equivalence Rationale:

The SafeAir Smoke Pencil and Accessories are either identical or similar in intended use, indications for use, technological characteristics, safety, and effectiveness to the previously cleared SafeAir Smoke Pencil. The products have the same fundamental scientific technology, basic design, functional characteristics and applications. The modifications and line extension of a coated electrode introduced raise no new questions of safety and effectiveness. Therefore, the SafeAir Smoke Pencil is at least as safe and effective as the predicate, and evidence supports a determination of substantial equivalence.